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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/541,247	07/01/2005	Mujun Zhao	SPT-0001	6598

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EXAMINER	
BOWMAN, AMY HUDSON	

ART UNIT	PAPER NUMBER
1635	

NOTIFICATION DATE	DELIVERY MODE
06/04/2008	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/541,247	ZHAO ET AL.	
	Examiner	Art Unit	
	AMY H. BOWMAN	1635	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *06 February 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-18* is/are pending in the application.

4a) Of the above claim(s) *1-5,8,9 and 11-16* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *6,7,10 and 17* is/are rejected.

7)☒ Claim(s) *18* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *01 July 2005* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Applicant's response filed 2/6/08 has been considered. Rejections and/or objections not reiterated from the previous office action mailed 9/6/07 are hereby withdrawn. The following rejections and/or objections are either newly applied or are reiterated and are the only rejections and/or objections presently applied to the instant application.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Applicant has added claims 16-18. Therefore, claims 1-18 are pending in the instant application.

Applicant argues that claim 11 depends from claim 7 and is directed to the same subject matter as those in claims 6, 7 and 10. It is noted that the subject matter of claims 6, 7 and 10 that is not directed to the elected invention, antisense polynucleotide for the hLRTM4 gene transcript was withdrawn as being directed to a non-elected invention. Claim 11 is not directed to the elected invention and is therefore withdrawn from consideration as explained in the office action mailed on 6/6/07.

Furthermore, although claims 8 and 9 are directed to a method of using the product of the elected group, the pending claims are not directed to only one of the categories listed below and thus unity of invention is lacking.

37 CFR 1.475(b) states:
"An international or a national stage application containing claims to different categories of invention will be considered to have unity of invention if the claims are drawn **only** to one of the following combinations of categories:

(1) A product and a process specially adapted for the manufacture of said product; or
(2) A product and process of use of said product; or
(3) A product, a process specially adapted for the manufacture of the said product, and a use of the said product; or
(4) A process and an apparatus or means specifically designed for carrying out the said process; or
(5) A product, a process specially adapted for the manufacture of the said product, and an apparatus or means specifically designed for carrying out the said process.

37 CFR 1.475(c) states:

"If an application contains claims to more or less than one of the combination of categories of invention set forth in paragraph (b) of this section, unity of invention might not be present."

37 CFR 1.475(d) also states:

"If multiple products, processes of manufacture or uses are claimed, the first invention of the category first mentioned in the claims of the application and the first recited invention of each other categories related thereto will be considered as the main invention in the claims, see PCT Article 17(3)(a) and 1.476(c)."

37 CFR 1.475(e) further states:

"The determination whether a group of inventions is so linked as to form a single general inventive concept shall be made without regard to whether the inventions are claimed in separate claims or as alternative within a single claim."

If the pending claims were directed to only one of the categories listed above, there would be unity of invention. Applicant asserts that it is improper to require restriction of dependent claims based on a passage that reads "unity of invention has to be considered in the first place only in relation to the independent claims in an international application and not the dependent claims...If the independent claims avoid the prior art and satisfy the requirement for unity of invention, no problem of lack of unity arises in respect of any claims that depend on the independent claims." However, in the instant case, the independent claims do not avoid the prior art and satisfy the requirement for unity of invention. Unity of invention was considered in the first place with respect to the independent claims, which lacked unity of invention.

This application contains claims 1-5, 8, 9, and 11-16, as well as the subject matter that is not directed to the elected invention (antisense polynucleotide for the hLRTM4 gene transcript) drawn to an invention nonelected with traverse in the reply filed on 6/15/07. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

Newly added claim 16 is withdrawn as being drawn to a nonelected invention because claim 16 recites that the antagonist is a small interfering RNA and therefore belongs with group IV.

Applicant's amendments and/or arguments filed 2/6/08, with respect to the rejection(s) of claim(s) under 35 USC 112 and 35 USC 102, have been fully considered and are persuasive. Therefore, the rejections have been withdrawn. However, upon consideration of the instant claim amendments, a new ground of rejection is applied as explained below.

Priority

Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file. It is noted that a translation of said papers has not been made of record.

Claim Objections

Claims 6, 7, 10, 17 and 18 are objected to because of the following informalities: Claims 6 and 7 recite subject matter that is directed to a non-elected invention, as

explained above. Claims 10, 17, and 18 are objected to because they depend from claim 7. Appropriate correction is required.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 6, 7, 10 and 17 are rejected under 35 U.S.C. 102(b) as being anticipated by Shimkets et al. (WO 01/47944 A2).

The instant claims are directed to a pharmaceutical composition comprising an antagonist of an HLRTM4 gene or gene transcript, wherein the hLRTM4 gene has a sequence of SEQ ID NO: 1, wherein the antagonist is a polynucleotide having a fragment of at least 15, 30, or 50 bases that hybridize to the hLRTM4 gene of the hLRTM4 gene transcript, and a pharmaceutically acceptable vehicle, diluent, or carrier.

Shimkets et al. teach a composition comprising an antisense polynucleotide sequence that is complementary and would therefore hybridize to 50 bases of the hLRTM4 gene transcript (see SEQ ID NO: 185 on page 50 of Shimkets et al., as well as sequence search result number 12 in SCORE file titled "20070803_131208_us-10-541-247-1.sl.rng"). Shimkets et al. teach compositions comprising the oligonucleotides of the invention with hybridization buffers and diluents, meeting the instant limitation of a pharmaceutically acceptable vehicle, diluent, or carrier.

Although Shimkets et al. does not teach that the antisense polynucleotide is "for the hLRTM4 gene transcript" and an antagonist of hLRTM4 gene transcript, as instantly recited, the antisense polynucleotide of Shimkets et al. meets all of the structural limitations of the instant claims and therefore meets the criteria of being "for the hLRTM4 gene transcript" and an antagonist thereof. As stated in the MPEP (see MPEP 2112), something that is old does not become patentable upon the discovery of a new property.

Therefore, the instant invention is anticipated by Shimkets et al.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to AMY H. BOWMAN whose telephone number is (571)272-0755. The examiner can normally be reached on Monday-Thursday 6:00 - 4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James (Doug) Schultz can be reached on (571) 272-0763. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Amy H. Bowman
Examiner
Art Unit 1635

AHB

/J. E. Angell/
Primary Examiner, Art Unit 1635